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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,034

12/16/2005

Masahiro Endo

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3565

29200

7590

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BAXTER HEALTHCARE CORPORATION

1 BAXTER PARKWAY

DF2-2E

DEERFIELD, IL 60015

EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

06/15/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

elizabeth\_eich@baxter.com

aida\_blekhman@baxter.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,034	<b>Applicant(s)</b> ENDO ET AL.	
	<b>Examiner</b> CATHERINE N. WITCZAK	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 13-45 is/are pending in the application.  
     4a) Of the above claim(s) 31-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-30 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/3/08; 2/4/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 recites the limitation "the plug" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3, 7- 10, 14-17, 19, 23, 24, , 26, 27, 30 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Deniega et al (US 2006/0149192).

Deniega et al discloses a catheter set comprising a catheter (58) having a plurality of side apertures (56) on an intraperitoneal end; an insert/tube (54) extending within the catheter and having a plurality of side apertures (element 54 is porous so it inherently has apertures) near the extraperitoneal end; a guidewire (46);

### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2, 4, 22, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al as modified by Klein et al (US 4,488,877).

Deniega et al disclose the claimed invention except for the catheter comprising a plug and a coiled intraperitoneal end. Klein et al teach in Figure 1 that it is known to use plug and a coiled catheter end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Deniega et al with a cuff as taught by Klein et al, since such a modification would ensure the catheter remained sanitary when not in use, and the coiled structure would provide for a more compact configuration in which to place the catheter inside a body.

3. Claims 11, 13, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al as modified by Basta (US 2004/199110).

Deniega et al disclose the claimed invention except for the catheter comprising a cuff for promoting tissue ingrowth. Basta teaches in Figure 2 that it is known to use a cuff. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Deniega et al with a cuff as taught by Basta, since such a modification would allow surrounding tissue to grow into the fabric of the cuff so as to stabilize that catheter.

4. Claims 6 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al as modified by Bolduc et al (US 2005/0245897).

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Deniega et al disclose the claimed invention except for the catheter set comprising radiopaque member. Bolduc et al teach in Figure 1 that it is known to use a radioopaque member (92). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Deniega et al with a cuff as taught by Bolduc et al, since such a modification would aid in positioning the system correctly.

5. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al as modified by Lazarus et al (US 4,479,792)

Deniega et al disclose the claimed invention except for a trocar secured to the device. Lazarus et al teach in Figure 1 that it is known to use a trocar in a catheter assembly. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Deniega et al with a trocar as taught by Lazarus et al, since such a modification would aid in the insertion of the set into a patient.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing

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date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witzak/  
Examiner, Art Unit 3767

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In view of the Appeal Brief filed on 1/7/2009, PROSECUTION IS HEREBY REOPENED. A new rejection is set forth above.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767.